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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by ANDREW M. CUOMO, Attorney General of the State of New York, and THE CITY OF NEW YORK,	**No.:** 07 Civ 8434
Plaintiffs,	
-against-	**DECLARATION OF VILIA B. HAYES**
MERCK & CO., INC.,	
Defendant.	

VILIA B. HAYES declares as follows:

1. I am an attorney admitted to practice before this Court and a member with the firm of Hughes Hubbard & Reed LLP, attorneys for defendant Merck & Co., Inc. ("Merck"). As such, I am fully familiar with the facts set forth herein. I make this declaration based on my own personal knowledge and the business records of the Firm.

2. I make this declaration in support of the Motion by Defendant Merck & Co., Inc. to Stay All Proceedings Pending Transfer Decision by the Judicial Panel on Multidistrict Litigation.

3. Attached hereto as Exhibit A is a true and correct copy of the Complaint in *Utah v. Merck & Co. Inc.*, No. 06-9336 (E.D. La.).

4. Attached hereto as Exhibit B is a true and correct copy of the Complaint in *Hood v. Merck & Co., Inc.*, No. 05-6755 (E.D. La.).

5. Attached hereto as Exhibit C is a true and correct copy of the Complaint in *Foti v. Merck & Co., Inc.*, No. 05-3700 (E.D. La.).

6. Attached hereto as Exhibit D is a true and correct copy of the Complaint in *Montana v. Merck & Co., Inc.*, No. 06-4302 (E.D. La.).

7. Attached hereto as Exhibit E is a true and correct copy of the Complaint in *Alaska v. Merck & Co., Inc.*, No. 06-3132 (E.D. La.).

8. Attached hereto as Exhibit F is a true and correct copy of the Complaint in *Franklin on behalf of the State of Colorado v. Merck & Co., Inc.*, No. 07-2073 (E.D. La.).

9. Attached hereto as Exhibit G is a true and correct copy of the Complaint in the present action, *New York v. Merck & Co., Inc.*, No. 07-8434 (S.D.N.Y.).

10. Attached hereto as Exhibit H are true and correct copies of the Transfer Order issued by the MDL Panel in MDL-1657, dated June 14, 2006; Transfer Order issued by the MDL Panel in MDL-1657, dated August 10, 2006; Transfer Order issued by the MDL Panel in MDL-1657, dated October 18, 2006; Transfer Order issued by the MDL Panel in MDL-1657, dated April 18, 2007; and Conditional Transfer Order issued by the MDL Panel in MDL-1657, dated December 6, 2005.

11. Attached hereto as Exhibit I is a true and correct copy of the Memorandum and Order issued in *Aguilar v. Merck & Co., Inc.*, No. 05-CV-4865 (SJ) (E.D.N.Y. Nov. 22, 2005).

12. Attached hereto as Exhibit J is a true and correct copy of the Order to Stay issued in *Reid v. Merck & Co., Inc.*, No. 6:05-cv-06621-DGL (W.D.N.Y. Mar. 1, 2006) and related cases.

13. Attached hereto as Exhibit K is a true and correct copy of the Order to Stay in *Campbell v. Merck & Co., Inc.*, No. 05-CV-6740L (W.D.N.Y. Mar. 1, 2006) and related cases.

14. Attached hereto as Exhibit L is a true and correct copy of the Memorandum Opinion and Order in *Pace v. Merck & Co., Inc.*, No. 04-1356 (D.N.M. Jan. 10, 2005).

15. Attached hereto as Exhibit M is a true and correct copy of the Minute Entry in *Falick v. Merck & Co., Inc.*, No. 04-3060 (E.D. La. Jan. 3, 2005).

16. Attached hereto as Exhibit N is a true and correct copy of the Order in *Montana v. Merck & Co., Inc.*, No. CV-06-07-H-DWM (D. Mont. May 12, 2006).

17. Attached hereto as Exhibit O is a true and correct copy of the Order in *Alaska v. Merck*, No. 3:06-cv-0018-TMB (D. Alaska Mar. 6, 2006).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Vilia B. Hayes

VILIA B. HAYES

Executed this
28th day of September, 2007

Exhibit A

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Attorneys for Plaintiff, State of Utah

IN THE THIRD JUDICIAL DISTRICT COURT OF SALT LAKE COUNTY

STATE OF UTAH

THE STATE OF UTAH, Plaintiffs, vs. MERCK & CO., INC., Defendant.	**COMPLAINT AND JURY DEMAND** **Civil No.** 060907140 **Judge** KOURIS

Plaintiff, the State of Utah (hereinafter "Plaintiff" or "the State"), by and through its Attorney General Mark L. Shurtleff, hereby complains of Defendant Merck & Co., Inc., (hereinafter "Defendant" or "Merck") and alleges as follows:

JURISDICTION AND VENUE

1. Jurisdiction over the subject matter of this cause of action is based upon the False Claims Act, Title 26, Chapter 20 of the Utah Health Code, which provides remedies to redress Defendant's actions under Utah Code Annotated § 26-20-1 et seq.

2. Personal jurisdiction over this Defendant is proper under the Utah Long Arm Statute as codified in §§ 78-27-22 and 78-27-24 of the Utah Code Annotated.

3. Venue is proper in the Third Judicial District and Salt Lake County pursuant to Utah Code Annotated § 78-13-7 in that many of the unlawful acts committed by Defendant were committed in Salt Lake County, including the making of false statements and misrepresentations of material fact to the State of Utah, its departments, agencies, instrumentalities and contractors, including the Utah Medicaid Program.

PARTIES

4. Plaintiff is the State of Utah in its capacity as sovereign and on behalf of the Division of Health Care Financing within the Utah Department of Health, the single state agency administering the Utah Medicaid Program.

5. Defendant Merck is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in Whitehouse Station, New Jersey. At all times relevant to this action, Merck was in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, the prescription pharmaceutical Vioxx (hereinafter "the product" or "Vioxx"). At all times relevant to this action, Merck did business within the State of Utah by marketing and selling Vioxx within the State to both the State and its agencies and to the general public.

NATURE OF THE CASE

6. This is a civil action for damages and civil penalties pursuant to Utah Code Annotated § 26-20-13.

ALLEGATIONS OF FACT

7. The Federal Food and Drug Administration (hereinafter "FDA") approved Vioxx on May 20, 1999, for the treatment of dysmenorrhea (painful menstrual cramps), management of acute pain in adults, and for relief of signs and symptoms of osteoarthritis. Subsequent to FDA approval, Vioxx was widely advertised and marketed by Merck as a safe and effective pain relief medication.

8. From the time Defendant started developing Vioxx, through the date of its withdrawal from the market on September 30, 2004, the Defendant engaged in knowing misrepresentations that Vioxx was safe and effective, as well as advertising and promotional campaigns that falsely represented the safety of Vioxx.

9. Defendant was aware of the serious and significant health hazards caused by Vioxx even before the medication was promoted to physicians, the State and the general public. Specifically, Defendant knew that cerebrovascular and cardiovascular problems occurred more frequently in patients receiving Vioxx than in patients receiving placebos or other medicines. Defendant's internal memos and e-mails dating back to at least 1996 show that the Defendant knew how and why Vioxx caused cardiovascular problems in Vioxx patients, as compared to a control group. This information was knowingly withheld or misrepresented to the FDA, the State and the general public. This information was material and relevant to Plaintiffs.

10. According to Merck, more than 52 million prescriptions have been written for Vioxx since 1999. Vioxx generated sales of 2.6 billion dollars in 2001 out of an anti-arthritic market of 5.5 billion dollars.

11. After Vioxx was approved and made available to the public, Merck sponsored the VIGOR (Vioxx Gastrointestinal Outcomes Research) study to obtain information regarding clinically meaningful gastrointestinal events and to develop a large controlled database for overall safety assessment. At the conclusion of the VIGOR study, it was reported that serious cardiovascular events occurred in 101 patients who took Vioxx, compared to 46 patients who took an over-the-counter alternative. Additionally, myocardial infarctions (heart attacks) occurred in 20 patients in the Vioxx treatment group, as opposed to only four in the alternative group.

12. In addition, Vioxx has been linked to several severe and life-threatening disorders including, but not limited to, edema, unsafe changes in blood pressure, heart attack, stroke, seizures, kidney and liver damage, pregnancy complications, meningitis and death. These dangers were not shared with physicians, the FDA, the State or the general public.

13. Beginning in the 1990s, Defendant's strategy was to aggressively market and sell Vioxx by willfully misleading potential users about serious dangers resulting from the use of Vioxx. Defendant undertook an advertising blitz, extolling the virtues of Vioxx in order to induce widespread use. This marketing campaign consisted of advertisements, telephone conferences, live conferences, direct promotional literature to doctors and other healthcare providers, and other promotional materials provided directly to Vioxx users.

14. The advertising program sought to create the impression and belief by consumers and physicians that Vioxx was safe for human use, and had fewer side effects and adverse reactions than other pain relief medications. This was done even though Defendant either knew these representations to be false or had no reasonable grounds to believe them to be true.

15. The advertising program purposefully downplayed the risks associated with Vioxx use, including serious illness and death. Merck relayed only positive information and relied upon manipulated statistics to suggest widespread acceptability, while at the same time concealing adverse factual material, including relevant information of serious health risks from the State, physicians and the general public. In particular, the advertising materials produced by Defendant falsely represented the severity, frequency and nature of adverse health effects caused by Vioxx. Further, they falsely represented that adequate testing had been done on Vioxx.

16. Merck's conduct was such that the FDA, which enforces federal statutes and regulations that require product safety disclosures to be truthful, fair and balanced, issued several informal warnings to Merck, requesting that accurate risk-related information be provided regarding Vioxx. These warnings went largely unheeded, prompting the FDA to write an official "warning letter" in September of 2001, demanding that Merck correct certain false and misleading claims.

17. As a result of Defendant's advertising and marketing efforts, Vioxx was pervasively prescribed throughout the United States and the State of Utah until September 30, 2004, when it was withdrawn from the market.

18. While making Vioxx available to Medicaid patients, Defendant knowingly misrepresented to the State, as well as to physicians and the general public that Vioxx was safe and efficacious. The State of Utah allowed the purchase of Vioxx for Utah Medicaid recipients based upon such representations by Defendant.

19. From May, 1999 until September 30, 2004, Vioxx was prescribed by Utah physicians to many recipients of the Medicaid Program of the State of Utah. As a result of ingesting Vioxx, Utah Medicaid patients suffered serious health effects now requiring further and more extensive medical treatment and provision of other health-related services. For these individuals, the State is the financially responsible party for this treatment. The State has thus suffered and will continue to suffer additional financial loss in the care of those Medicaid recipients who consumed prescriptions which were ineffective, unsafe and actively harmful.

20. The Utah Attorney General has the right to bring this suit pursuant to Utah Code Annotated §§ 26-20-13(2)(a), 67-5-1(2) and 67-5-3. Utah Code Annotated § 26-20-9.5(1)(b) further provides that the State of Utah is entitled to recover the costs of enforcement in this case, including but not limited to the cost of its investigators and attorneys.

FIRST CLAIM FOR RELIEF
(Strict Products Liability – Failure to Warn)

21. Plaintiff incorporates paragraphs 1 through 20 as if fully set forth herein, and further alleges as follows:

22. Defendant is the manufacturer and/or supplier of Vioxx.

23. The Vioxx manufactured and/or supplied by Defendant was unaccompanied by proper warnings or packaging regarding all possible side effects associated with the use of

Vioxx. The Defendant failed to warn of the comparative severity, incidence and duration of such adverse effects. The warnings given to the State, physicians and the general public did not accurately reflect the signs, symptoms, incidents or severity of the side effects of Vioxx.

24. Defendant failed to adequately test Vioxx. Such testing would have further confirmed that Vioxx possessed serious potential side effects to which full and proper warnings should have been made.

25. The Vioxx manufactured or supplied by Defendant was defective due to inadequate post-marketing warnings, packaging or instructions. After the manufacturer knew or should have known of the risks of injury from Vioxx, it failed to provide adequate warnings to physicians, the general public or the State as the prescribers, users and financially responsible party, respectively. Further, Defendant continued to aggressively market Vioxx.

26. As a proximate cause and legal result of Defendant's failure to warn of known and reasonably knowable dangers associated with the use of Vioxx, the State of Utah has suffered and will continue to suffer damages as outlined in paragraph 19 above. The State is therefore entitled to recover for those damages, as well as those outlined in paragraph 20.

27. Based on information and belief, Defendant actually knew of the defective nature of Vioxx, but continued to market and sell Vioxx without proper warning, so as to maximize sales and profits, in conscious disregard for the foreseeable harm caused by Vioxx.

28. Defendant's conduct in the advertising, marketing, promotion, packaging and distribution of Vioxx without proper and timely warnings was fraudulent and knowing or reckless misconduct, with conscious disregard for the safety of consumers and the State as the

financially responsible party. The same constitutes oppression, fraud and malice sufficient to entitle the State to an award of punitive damages in an amount sufficient to punish Defendant and set an example to all drug manufacturers who represent the safety of their product to the State for use in the Medicaid Program.

SECOND CLAIM FOR RELIEF
(Strict Products Liability: Design Defect)

29. Plaintiff incorporates paragraphs 1 through 28 as if fully set forth herein, and further alleges as follows:

30. At all times material and relevant to this action, Vioxx was defective in design and manufacture, and was so at the time it was prescribed by doctors participating in the State's Medicaid Program. Vioxx was defective and dangerous in that it caused serious injuries when used for its intended and foreseeable purpose, i.e., when ingested as prescribed and in the manner recommended by Defendant.

31. The defects in Vioxx were known to Defendant at the time of approval by the FDA. Such defects were concealed and withheld from the FDA. Disclosure by Defendant was inaccurate, incomplete, misleading and fraudulent.

32. Defendant knew Vioxx would be used by the consumer without inspection for defect and that the State, physicians and medicinal users of Vioxx were relying upon Defendant's representations that the product was safe.

33. Adequate post-approval testing would have revealed the further extent of the dangers of ingesting Vioxx, and would have shown that Vioxx was unsafe for human

consumption and could cause extensive medical complications and costs for injuries relating to its use.

34. As a proximate and legal result of the design defect, as well as Defendant's failure to adequately test the product so as to discover the defect, the State of Utah has suffered and will continue to suffer the damages alleged in paragraph 19, and is therefore entitled to recover for those damages as well as those outlined in paragraph 20.

35. Defendant's conduct in the design and testing of this drug was fraudulent, reckless, and undertaken with conscious disregard for the rights and safety of others, including the State of Utah. The State is therefore entitled to an award of punitive damages, to punish and make an example of Defendant as set forth in paragraph 28 above.

THIRD CLAIM FOR RELIEF
(Fraud and Negligent Misrepresentation)

36. Plaintiff incorporates paragraphs 1 through 35 as if fully set forth herein, and further alleges as follows:

37. Defendant's warning of side effects associated with Vioxx contained false representations and/or failed to accurately represent the material facts of the full range and severity of side effects and adverse reactions associated with the product.

38. Defendant's claims and assertions to the FDA, the State of Utah, physicians and the general public regarding Vioxx contained false representations as to the safety of Vioxx and its defective design.

39. Defendant was negligent in not making accurate representations regarding the side effects and adverse medical conditions caused by the use of Vioxx.

40. Defendant knew or reasonably should have known through adequate testing that the claims made to the State with respect to the safety of Vioxx were false or incomplete, and misrepresented the material facts regarding the unsafe and defective condition of Vioxx.

41. Defendant's misrepresentations in this regard were done with the intention of inducing the State to approve of the distribution of Vioxx to participants in the Utah Medicaid Program.

42. As a proximate and legal result of Defendant's fraudulent misrepresentations, the State of Utah has suffered and will continue to suffer the damages alleged in paragraph 19, and is therefore entitled to recover for those damages, as well as those outlined in paragraph 20.

43. Defendant's conduct in making these fraudulent representations was deliberate and undertaken with conscious disregard for the rights and safety of others, including the State of Utah. The State is therefore entitled to an award of punitive damages, to punish and make an example of Defendant as set forth in paragraph 28 above.

FOURTH CLAIM FOR RELIEF
(Negligence)

44. Plaintiff incorporates paragraphs 1 through 43 as if fully set forth herein, and further alleges as follows:

45. Defendant had a duty to exercise reasonable care in the manufacture, sale, and/or distribution of Vioxx, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed or misrepresented side effects. This duty extends to the State of Utah as the party ultimately bearing financial responsibility for Utah Medicaid patients.

46. Defendant breached this duty, as it was negligent in the testing, marketing, manufacture, sale and packaging of Vioxx.

47. As a direct and proximate result of Defendant's negligence, the State of Utah has suffered and will suffer the damages alleged in paragraph 19 above, and is entitled to recover for those damages as well as the damages outlined in paragraph 20.

48. Defendant's negligence in testing, manufacturing, packaging, and marketing Vioxx was fraudulent, reckless, and undertaken with conscious disregard for the rights of others, including the State of Utah. Plaintiff is therefore entitled to an award of punitive damages to punish and make and example of Defendant as set forth in paragraph 28.

FIFTH CLAIM FOR RELIEF
(Breach of Express Warranty)

49. Plaintiff incorporates paragraphs 1 through 48 as if fully set forth herein, and further alleges as follows:

50. In marketing Vioxx and making it available through the Utah Medicaid Program, Defendant expressly warranted to the State, its physicians and Medicaid recipients that Vioxx was safe, effective, fit and proper for its intended use. Pursuant to Utah Code Annotated § 70A-2-313, these express warranties were created by and through statements made by Defendant or Defendant's authorized agents or sales representatives, orally and in publications, package inserts, and in other written materials intended for the State, physicians, medical patients and the general public.

51. The State, its physicians and Medicaid patients relied on the skill, judgment, representations and foregoing express warranties. Such representations were false in that Vioxx was not safe or fit for its intended use.

52. As a direct and legal result of this breach of warranty, the State of Utah has suffered and will continue to suffer damages as set forth in paragraph 19 above. Pursuant to Utah Code Annotated §§ 70A-2-714 and 70A-2-715, the State is therefore entitled to recover those damages, including incidental and consequential damages, from Defendant.

SIXTH CLAIM FOR RELIEF

(Breach of Implied Warranty)

53. Plaintiff incorporates paragraphs 1 through 52 as if fully set forth herein, and further alleges as follows:

54. Pursuant to Utah Code Annotated § 70A-2-314, through the manufacture, marketing, and sale of Vioxx, Defendant impliedly warranted to the State of Utah, its physicians and its Medicaid recipients that Vioxx was of merchantable quality – safe and fit for the use for which it was intended.

55. At all times relevant to this action, Defendant had reason to know of the particular purpose for which the State, its physicians and Medicaid recipients were purchasing and using Vioxx, i.e., for the safe and effective treatment of pain. Therefore, pursuant to Utah Code Annotated § 70A-2-315, Defendant impliedly warranted to the State of Utah, its physicians and its Medicaid recipients that Vioxx was fit for that particular purpose.

56. Defendant had reason to know through actual or constructive knowledge that the State of Utah, its physicians and Medicaid recipients were reasonably relying upon the skill, judgment and implied warranties of Defendant in allowing the use of Vioxx.

57. Defendant breached the implied warranties of merchantability and of fitness for a particular purpose in that Vioxx was neither safe for its intended use nor of merchantable quality, nor was it safe for the particular purpose intended by the State and Medicaid recipients, in that Vioxx had dangerous propensities when put to its intended use, resulting in severe illness and injury to many of its users.

58. As a direct and legal result of this breach of warranty, the State of Utah has suffered and will continue to suffer damages as set forth in paragraph 19 above. Pursuant to Utah Code Annotated §§ 70A-2-714 and 70A-2-715, the State is therefore entitled to recover those damages, including incidental and consequential damages, from Defendant.

SEVENTH CLAIM FOR RELIEF
(Negligence *Per Se*)

59. Plaintiff incorporates paragraphs 1 through 58 as if fully set forth herein, and further alleges as follows:

60. Defendant has an obligation not to violate the law.

61. Defendant has violated the Federal Food, Drug, and Cosmetic Act as set forth in 21 U.S.C. 301, *et seq.*, its related amendments, codes, and federal regulations promulgated thereunder, and other applicable state and federal law.

62. Medicaid patients, as purchasers and consumers of the product, and the State of Utah, as the financially responsible party, are within the class of persons that the statutes

described above are designed to protect. Injury due to design defect, misbranding, false advertising and misleading products is the type of harm these statutes are intended to prevent.

63. Defendants failed to meet the standard of care set by the following regulations, which were intended for the benefit of patients and the State of Utah as the responsible paying party, making Defendant negligent *per se*:

a. The labeling lacked adequate information on the intended use of Vioxx, even though Defendant was aware of the widespread use of Vioxx, in violation of 21 C.F.R. 201.56(a) and (b);

b. The labeling did not state there was a lack of evidence to support the common belief in the safety and efficacy of Vioxx in violation of 21 C.F.R. 201.57(c)(3)(i);

c. The labeling failed to add warnings of the serious side effects including, but not limited to, cardiovascular events, strokes, heart attacks and death as soon as there was reasonable evidence of their association with Vioxx in violation of 21 C.F.R. 201.57(e);

d. The labeling contained inadequate information for patients and physicians to determine the safe and effective use of Vioxx in violation of 21 C.F.R. 201.57(f)(2);

e. The labeling contained inadequate information regarding the level of care and monitoring to be exercised by the doctor for safe and effective use of Vioxx in violation of 21 C.F.R. 201.57(f)(1);

f. Vioxx' labeling and promotion was misleading in violation of 21 C.F.R. 201.56(b);

g. Defendant's advertisements contained untrue and misleading information and/or failed to contain true and accurate statements relating to the side effects, contraindications and effectiveness of Vioxx in violation of 21 C.F.R. 202.1(e), and;

h. Defendant's advertisements for Vioxx were false, lacking in fair balance or otherwise misleading in violation of 21 C.F.R. 202.1(e)(7).

64. Defendant is responsible to the State for economic loss incurred for violations of the statutes and regulations described above under the doctrine of negligence *per se*.

65. As a direct and proximate result of the violations of these statutes, the State of Utah has suffered and will continue to suffer damages as alleged in paragraph 19 above, and is therefore entitled to recover for those damages, as well as the damages outlined in paragraph 20.

EIGHTH CLAIM FOR RELIEF
(Civil Penalties Under the Utah Health Code)

66. Plaintiff incorporates paragraphs 1 through 65 as if fully set forth herein, and further alleges as follows:

67. Defendant violated the False Claims Act of the Utah Health Code as codified in Title 26, Chapter 20 of the Utah Code Annotated. These violations were committed in the following particulars:

a. Defendant made "false statements" or false representations to the State and its agencies in seeking inclusion and payment under the Utah Medicaid Program, in violation of Utah Code Annotated § 26-20-3;

b. Defendant caused false and fraudulent claims for benefit to be made to employees and officers of the State in order to secure inclusion and payment under the Medicaid Program, in violation of Utah Code Annotated § 26-20-7(1);

c. the documentation given by Defendant to the State regarding the safety and efficacy of Vioxx for inclusion and payment under the Medicaid Program was falsified or altered with intent to deceive, in violation of Utah Code Annotated § 26-20-7(2)(j);

d. Defendant's claims to the State for inclusion and payment under the Medicaid Program misrepresented the type and quality of the services rendered by the ingestion of Vioxx, in violation of Utah Code Annotated § 26-20-7(2)(b); and

e. Defendant filed claims for inclusion and payment under the Medicaid program for services and/or goods which it knew were not medically necessary, in violation of Utah Code Annotated § 26-20-7(2)(d).

68. Under the provisions of Utah Code Annotated § 26-20-9.5, Defendant is liable for the following damages:

a. full and complete restitution to the state of all medical benefits improperly obtained;

b. the costs of enforcement, including but not limited to the cost of investigators and attorneys;

c. a civil penalty not to exceed three times the value improperly claimed; and

d. a civil penalty of up to $2,000.00 for each violation.

69. These costs and penalties are in addition to and not a substitute for the damages alleged in paragraph 19 and 20 above.

JURY DEMAND

The State respectfully requests a trial by jury pursuant to Rule 38, Utah R. Civ. Proc.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the State of Utah, prays for judgment against Defendant as follows:

1. an award to Plaintiff in the form of judgment against Defendant Merck for the Vioxx-related damages of past, present and future medical expenses for recipients of the Utah Medicaid Program;

2. the cost of all Vioxx prescriptions paid by the Utah Medicaid Program;

3. for all civil penalties pursuant to the statutes cited herein;

4. for the costs of enforcement pursuant to § 26-20-9.5(b), Utah Code Ann.;

5. for punitive damages for the wanton and reckless conduct of Defendant as outlined herein;

6. for exemplary damages for the benefit of all other drug manufacturers who wrongly misrepresent the safety of their product to the detriment of the State's Medicaid Program;

7. For such other and further relief as may be justified and which Plaintiff may be entitled to by law including, but not limited to, all court costs, witness fees and deposition fees.

Respectfully SUBMITTED and DATED this 27th day of April, 2006

Mark L. Shurtleff
Attorney General of Utah

David R. Stallard

David R. Stallard
Assistant Attorney General

GARRETSON & STEELE, LLC
Matthew L. Garretson
Joseph W. Steele

ATTORNEYS FOR THE STATE OF UTAH

Exhibit B

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF
HINDS COUNTY, MISSISSIPPI

JIM HOOD, ATTORNEY GENERAL *ex rel.*,
STATE OF MISSISSIPPI

PLAINTIFF

v.

CIVIL ACTION NO.: G2005-1712 w/f

MERCK & CO., INC.

DEFENDANT

COMPLAINT

The State of Mississippi, through Attorney General Jim Hood, brings this action for monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits and punitive damages on behalf of the State of Mississippi, and on behalf of Mississippi citizens who have paid for the prescription drug Vioxx®, manufactured and marketed by the Defendant, Merck & Co., Inc., as more fully described below:

INTRODUCTION

1. Defendant, Merck & Co., Inc., ("Merck"), has defrauded the State of Mississippi, its agencies and instrumentalities, by knowingly issuing false and misleading statements in order to induce the State, its agencies and instrumentalities to purchase its drug VIOXX®.

2. VIOXX® is a Cox-2 specific inhibitor used in the treatment of inflammation and pain and is among the class of drugs known as NSAIDs. Traditional NSAIDs inhibit both Cox-1 and Cox-2 enzymes. Cox–1 enzyme is believed to have a protective effect on the gastrointestinal system and the traditional NSAIDs were known to pose a risk of ulcer and other gastrointestinal problems. It is alleged herein that Defendant, misrepresented that VIOXX® had a significantly reduced risk of these side effects.

3. VIOXX® was promoted and marketed by Defendant, Merck & Co., Inc., ("Merck") as much safer and more effective drug than the much cheaper NSAIDs already on the

market. In reliance on these claims by Defendant, agencies and instrumentalities of the State approved the inclusion of VIOXX® as a preferred prescription drug and agreed to pay for use of VIOXX® by beneficiaries and members. Defendant initially misrepresented the safety of the drug in order to obtain a position on the State's prescription drug formularies, so that it would be able to obtain a large share of the market for these types of drugs.

4. Defendant's representations that VIOXX® was safer than traditional NSAIDs was false, and despite its marketing and promotion as a safer alternative to traditional NSAIDs, VIOXX® also posed a risk of ulcers and gastrointestinal side effects. Moreover, VIOXX® produced a high rate of cardiovascular events, including heart attacks and strokes, and Defendant intentionally failed to disclose the level of risk of cardiovascular events caused by the drug.

5. Defendant was aware that by their false and misleading marketing and sales practices they would be able to prevent Mississippi agencies and instrumentalities and Mississippi physicians and its citizens from discovering, through reasonable diligence, the true risks associated with the ingestion of VIOXX®.

6. Fair and honest marketing of pharmaceuticals is a matter of great importance to the State of Mississippi and its citizens. Mississippi spends millions and millions of dollars each year on prescription drugs under its prescription drug programs. Expenditures by the State and its agencies and instrumentalities for prescription drug reimbursement have increased dramatically in the past several years as a result of Defendant's marketing schemes.

7. Plaintiff, the State of Mississippi (the "State"), by and through Mississippi Attorney General Jim Hood, brings this action:

(a) to recover amounts paid for the drug VIOXX® by the State, through its agencies and instrumentalities, as a result of the fraudulent conduct of Defendant;

(b) to recover the amounts the State has paid for its percentage share of VIOXX®, on behalf of the Mississippi citizens who are eligible for Medicaid;

(c) to recover the costs incurred by the State through its agencies and instrumentalities, relating to the medical treatment rendered to beneficiaries of State programs, and reimbursed by the State, as a result of the ingestion of VIOXX®; and

(d) to enjoin Defendant from continuing to perpetrate these marketing practices, to require Defendant to publicly disclose the true and actual risks of its drugs to potential users and purchasers, and to impose civil penalties against Defendant for its fraudulent practices.

PARTIES

8. Mississippi Attorney General Jim Hood is authorized to bring this action on behalf of the State under the Mississippi Constitution of 1890, pursuant to Mississippi statutes providing for certain of the causes of action herein, including, among others, § 7-5-1, Miss. Code Ann. (1972) and § 43-13-1 through § 43-1-145, Miss. Code Ann. (1972), as well as by common law.

9. Defendant, Merck & Co., Inc., "Merck" is a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey. Merck is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are reimbursed by State Medicaid agencies nationwide, including Mississippi's Division of Medicaid. Numerous pharmaceuticals are sold by Merck and reimbursed by the State under Mississippi's Medicaid program, and these drugs included VIOXX®. The State, through its agencies and instrumentalities has paid millions of dollars for reimbursement of such drugs manufactured by Merck.

JURISDICTION AND VENUE

10. Jurisdiction is proper as Plaintiff alleges only claims arising under the laws of the State of Mississippi. Venue is proper in the First Judicial District of Hinds County, Mississippi, pursuant to Mississippi statutory authority, including, § 43-13-223, § 43-13-301, § 75-24-9, Miss. Code Ann. (1972).

FACTUAL BACKGROUND

11. The State, through programs administered by its various agencies and instrumentalities pays for medical benefits, including prescription drugs, for qualifying Mississippians. These programs reimburse physicians and pharmacists for drugs prescribed for, and dispensed to, qualified recipients.

12. Reimbursement for prescription drugs under State programs are authorized by statute, for example, § 43-13-117 Miss. Code Ann. (1972). Pursuant to statute, the State agencies and instrumentalities have adopted a list of drugs which are covered without prior authorization. In determining which drugs will be included on the list, the administrators of the State's programs consider information provided by prescription drug manufacturers regarding the safety of the drug and the efficacy of the drug as compared to less expensive alternatives.

13. When a drug manufacturer reports false and misleading information concerning the safety of its product, and its effectiveness as compared with less expensive alternative drugs, and/or conceals this information from physicians and the State agencies and instrumentalities, the determination made by the agencies and instrumentalities with respect to the drug's inclusion on its preferred drug list or reimbursable formulary is flawed. These circumstances result in drug reimbursement payments to drug providers by the State of Mississippi for drugs which should not have been approved for prescription by medical providers. At all times relevant to this

action, Defendant was aware of the State agencies' drug utilization review, approval and reimbursement formulas.

14. Defendant provided to the State and its agencies and its instrumentalities, directly and/or through submission of reports to drug utilization review committees, what was purported to be accurate data for the Merck product, VIOXX®. In addition, Merck's intense marketing and sales efforts directed directly at the State of Mississippi, and to the general public, were carried out in such a manner as to create the false perception by the public, generally, and Mississippians, specifically, that its drug VIOXX® was safe, effective, and a better source of pain relief than other less expensive alternative medications.

15. Defendant has affirmatively endeavored to conceal the actual nature of the drug VIOXX®, its attendant risks, and its lack of reported efficacy. As a result of this concealment, Defendant prevented third parties, including the State of Mississippi and its agencies and instrumentalities, from determining the true nature of the drug VIOXX®, and at all times relevant to this action, Defendant knew that information accurately reflecting the dangers associated with VIOXX® and its lack of substantial effectiveness as compared to other drugs was not available to the State and its agencies and instrumentalities. Defendant was aware that at all relevant times, the State's agencies used, and relied on, the information regarding VIOXX® as provided by Defendant to the State and its agencies, directly and indirectly, to determine the amounts paid for reimbursement of prescription drugs.

16. Defendant intended that the drug information provided to the State and its agencies, both directly and indirectly, would be used by the State and its agencies to determine whether VIOXX® would be on the State's formulary, and in what amount the various State programs would reimburse pharmacy providers for VIOXX®.

17. At all relevant times, the State, its agencies and instrumentalities had no knowledge of, and had no means of learning, the actual nature and efficacy of VIOXX®. Rather, the State, its agencies and instrumentalities obtained this information from Defendant, directly and indirectly, and reasonably relied on this information in determining the State's pharmacy benefits relative to VIOXX®.

DEFENDANT'S FALSE AND MISLEADING STATEMENTS

A. 1999 False and Misleading Statements.

18. During the time period from May 21, 1999, when VIOXX® was first introduced on the market, through December 1999, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Announces FDA Approval of VIOXX®

19. On May 21, 1999, Merck issued a press release (the "May 21, 1999 Press Release") in which it announced that the FDA had approved VIOXX® for the relief of osteoarthritis, menstrual pain and other forms of acute pain. Merck stated that the most common side effects reported in clinical trials with VIOXX® were upper-respiratory infection, diarrhea and nausea. The press release stated that VIOXX® should be available in pharmacies by mid-June, 1999. The press release failed to disclose material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX®. Defendant was aware of these risks from internal studies, including Study 090, the results of which Defendant failed to disclose to the FDA or to the public.

2. Merck Promotes VIOXX® while Purposely Failing to Disclose The Cardiovascular Risks of the Drug

20. On October 19, 1999, the Company issued a press release entitled "Publication shows new medicine VIOXX® relieved Menstrual Pain" (the "October 19, 1999 Press Release".) The October 19, 1999 Press Release stated in pertinent part "Since its approval by the FDA in May, more than 2.2 million prescriptions have been written for VIOXX® in the United States, making it one of the most successful product introductions in the pharmaceutical industry's history." The October 19, 1999 Press Release failed to disclose material adverse information known to Merck concerning the serious cardiovascular risks associated with VIOXX®.

21. On October 25, 1999, the Company issued a press release (the "October 25, 1999 Press Release") in which the Company stated that VIOXX® "produced fewer ulcers in osteoarthritis patients than patients taking ibuprofen." Merck announced the results of a new study showing that osteoarthritis patients taking VIOXX® developed fewer stomach ulcers than patients taking ibuprofen. The October 25, 1999 Press Release failed to disclose the material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX® that threatened VIOXX®'s medical and commercial viability.

22. On November 23, 1999, the Company issued a press release (the "November 23, 1999 Press Release") entitled "In a Study Published in the Journal of the American Medical Association, VIOXX® Significantly Reduced Risk of Serious Gastrointestinal Side Effects Compared to Other NSAIDS." The November 23, 1999 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> VIOXX®, the new medicine for osteoarthritis from Merck & Co., Inc., significantly reduced the risk of gastrointestinal (GI) side effects such as symptomatic ulcers and bleeding compared to three

> commonly prescribed non-steroidal anti-inflammatory drugs (NSAIDs), according to a new study being published in tomorrow's issue of the Journal of the American Medical Association.
>
> ***
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> Common side effects reported in clinical trials with VIOXX® were upper-respiratory infection, diarrhea, nausea and high blood pressure. People who have had an allergic reaction to VIOXX®, aspirin or other NSAIDs should not take VIOXX®. Safety and effectiveness in children below the age of 18 has not been studied.

23. The November 23, 1999 Press Release failed to disclose material adverse information concerning cardiovascular risks associated with VIOXX®, including results of Study 090 which concluded that VIOXX® users were 6 times more likely than non-VIOXX® users to have severe cardiovascular events.

24. Each of the Defendant's statements made in 1999 concerning VIOXX® was materially false and misleading when issued, because each statement failed to disclose information known to the Defendant, that VIOXX® was associated with negative cardiovascular events. The true but concealed and/or misrepresented facts included, but were not limited to:

- Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than users of other NSAIDS;
- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, Merck knew of the VIOXX®-related medical risks;
- Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs;
- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence; and
- The Company could not maintain the positive VIOXX® sales results that it was experiencing because of the known risks to VIOXX®'s medical and commercial viability.

B. 2000 Events and False and Misleading Statements

25. In 2000, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Announces Results of VIGOR Study, But Conceals Findings of Cardiovascular Risks Associated with VIOXX®

26. On March 27, 2000 Merck issued a press release (the "March 27, 2000 Press Release") entitled "Merck Informs Investigators of Preliminary Results of Gastrointestinal Outcomes Study With VIOXX®." The March 27, 2000 Press Release commented upon the results of the VIGOR study previously discussed in this Complaint. In the March 27, 2000 Press Release, Merck stated that according to the VIGOR study results, "[a]mong patients treated with VIOXX®, there was a significantly reduced incidence of serious gastrointestinal events compared to patients treated with Naproxen." The March 27, 2000 Press Release also made the following materially false and misleading statements and/or omissions of material facts:

> In addition, significantly fewer thromboembolic events were observed in patients taking Naproxen in this GI outcomes study, which is consistent with Naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for Naproxen. **VIOXX®, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.** As a result, Merck is notifying investigators, who are conducting other Merck studies with VIOXX® or another investigational medicine in the same class, of protocol amendments to allow the addition of low-dose aspiring where appropriate.
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> An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX®, **showed no indication of a difference in the incidence of thromboembolic events between VIOXX®, placebo and comparator NSAIDs** (emphasis added).

27. The March 27, 2000 Press Release failed to disclose known material negative information concerning the cardiovascular risks associated with VIOXX® that threatened VIOXX®'s medical and commercial viability. Moreover, the March 27, 2000 Press Release misleadingly and falsely attributed the higher incidence of cardiac events observed in the VIGOR study to the putative cardio protective characteristics of Naproxen.

3. Merck Falsely Touts VIOXX®'s Safety Profile as "Excellent"

28. On September 8, 2000, Merck issued a Press Release (the "September 8, 2000 Press Release") entitled "Merck Confirms Excellent Safety Profile of VIOXX®." In the September 8, 2000 Press Release, Defendant made the following materially false and misleading statements and/or omissions of material fact:

> Merck & Co., Inc. confirmed today that a routine report issued by the U.K. regulatory authority demonstrates the excellent safety profile of VIOXX® (rofecoxib), Merck's medicine for osteoarthritis. The report was issued by the U.K. Medicines Control Agency (MCA) because VIOXX® has now been available in the U.K. for one year. During that time, more than 550,000 prescriptions for VIOXX® were written for patients in the U.K. The events listed were reported by physicians as events that occurred while patients were taking VIOXX®, and were not specifically attributed to VIOXX®.
>
> **Merck considers patients safety to be of the utmost importance, and we routinely monitor all of our medicines. What was reported by the MCA confirms what we've seen in the thousands of patients in our controlled clinical trials and in clinical practice: VIOXX® has an excellent safety profile,** says Eve Slater, M.D. senior vice president, Clinical and Regulatory Development, Merck Research Laboratories. (emphasis added)

29. The September 8, 2000 Press Release failed to disclose material adverse information known to Merck regarding the cardiovascular risks associated with VIOXX®, including the results of Study 090 and VIGOR which showed that VIOXX® presented a high risk of negative cardiovascular events.

30. On November 3, 2000, Defendant issued a press release (the "November 3, 2000 Press Release") entitled "VIOXX® Significantly Reduced Pain After Dental Surgery to a Greater Degree Compared to Codeine with Acetaminophen in New Study." In the November 3, 2000 Press Release, Defendant announced the results of a study which showed that "VIOXX® 50mg significantly reduced moderate to severe acute pain after dental surgery to a greater degree compared to codeine 60 mg combined with acetaminophen 600 mg." The November 3, 2000 Press Release stated in pertinent part:

> "Overall, VIOXX® was well tolerated in this study, and overall rate of side effects on VIOXX® was generally similar to placebo. Significantly fewer patients taking VIOXX® experienced side effects than patients taking codeine with acetaminophen."

31. The November 3, 2000 Press Release failed to disclose material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX®.

32. Each of the Defendant's statements made from January 1, 2000 through December 31, 2000 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose material and statistically significant information known to the Company that VIOXX® was associated with cardiovascular events. In this regard, the Merck Defendant failed to disclose:

- Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;
- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, Merck knew of the VIOXX®-related medical risks;
- Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs; and
- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional

materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• The Merck Defendant knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendant observed in Study 090 and VIGOR; and

• VIOXX®'s safety profile was not "excellent" as the Merck Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

C. 2001 Events and False and Misleading Statements

33. In 2001, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Announces the FDA Advisory Committee Meeting To Modify VIOXX® Label

34. On February 8, 2001, Merck issued a press release (the "February 8, 2001 Press Release") entitled "FDA Arthritis Advisory Committee Reviews Merck's Application for Revised Labeling for VIOXX® Based on VIOXX® Gastrointestinal Outcomes Study." In the February 8, 2001 Press Release, Merck announced that the FDA Advisory Committee had agreed that results from the VIGOR study -- that VIOXX® significantly reduced serious GI side effects by half compared to a commonly used dose of Naproxen in rheumatoid arthritis patients -- be included in the labeling for VIOXX®. The February 8, 2001 Press Release made the following materially false and misleading statements:

> Merck is confident that the data presented today support the excellent safety profile of VIOXX®, and we look forward to further discussions with the FDA to complete the review of our application to modify the labeling for VIOXX®, said Eve Slater, M.D., senior vice president, Clinical and Regulatory Development, Merck Research Laboratories.

35. The February 8, 2001 Press Release failed to disclose known information concerning significantly increased risks of cardiovascular problems associated with VIOXX®, and failed to disclose that VIOXX® had, at best, a questionable safety profile.

2. Merck Touts FDA Approval of Revised Label for VIOXX®

36. On April 10, 2001, Merck issued a press release (the "April 10, 2001 Press Release") entitled "Merck Receives 'Approvable' Letter for VIOXX® from FDA on Application for Revised Labeling Based on VIOXX® Gastrointestinal Outcomes Study." The April 10, 2001 Press Release contained the following materially false and misleading statements and omissions of material fact:

> Merck & Co., Inc. today confirmed that it has received an approvable letter from the U.S. Food and Drug Administration for the Company's application for changes to the prescribing information for its osteoarthritis and acute pain medicine VIOXX® (rofecoxib).
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> ***
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> The Company submitted a supplemental new drug application on June 29, 2000, seeking changes to reflect results from the VIOXX® Gastrointestinal Outcomes Research (VIGOR) study. The Company is confident in the comprehensive data that support the excellent gastrointestinal and overall safety profile of VIOXX®.

37. This press release failed to disclose what the Merck Defendant knew at the time to be a significant risk of serious cardiovascular events.

38. On May 1, 2001, *Med Ad News* published an article entitled "Determined to overtake rival Celebrex, Merck has made VIOXX® the fastest-growing brand," in which a senior Vice President of marketing at Merck, was quoted as stating:

> VIOXX® has broken the traditional new nonsteroidal anti-inflammatory drug shape of the curve because the product has continued to grow way beyond the normal six-month time frame when the older new nonsteroidal anti-inflammatory drugs and even Celebrex tended to flatten off. VIOXX® has continued to grow and that is a result of the good product that we have, the satisfaction that it is providing to patients and physicians, and the strong marketing and marketing messages that we have put into the marketplace.

39. The foregoing statement by the Defendant failed to disclose material adverse information known to it concerning the cardiovascular risks associated with VIOXX®. The statements by the Defendant were directly contradicted by its internal e-mails and documents and by Merck-sponsored studies described elsewhere herein.

40. On May 11, 2001, Merck issued a press release (the "May 11, 2001 Press Release") entitled "Merck Confirms Renal Safety Of VIOXX®." The May 11, 2001 Press Release stated that in comparative studies between VIOXX®, celecoxib and acetaminophen, there were no significant differences in the incidents of renal effects, such as hypertension and edema, and that "in these studies, the incidences of increased blood pressure and lower extremity edema among patients taking VIOXX® were similar to those of the comparator NSAIDs; there were no significant differences between the active treatment groups." The May 11, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the cardiovascular risks associated with VIOXX®, including those specifically revealed by this Merck sponsored study.

41. On May 22, 2001, Merck issued a press release (the "May 22, 2001 Press Release") entitled "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX®." In the May 22, 2001 Press Release, the Company made the following materially false and misleading statements:

> In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of VIOXX® (rofecoxib), its medicine that selectively inhibits COX-2.

42. The May 22, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the cardiovascular risks associated with VIOXX®. Among other things, the Defendant failed to disclose the contents of Merck internal e-mails and

documents, Study 090, the VIGOR study, the results of Merck-sponsored research and studies, and the conclusions that Merck aggressively sought to sponsor.

3. Merck Promotes False Cardiovascular Safety Profile of VIOXX®

43. On June 13, 2001, Merck issued a press release (the "June 13, 2001 Press Release") entitled "In New 28,000-Patient Meta-Analysis of Cardiovascular Events: Event Rates With VIOXX® were Similar to Placebo, Similar to Widely Prescribed NSAIDs Ibuprofen, Diclofenac and Nabumetone; Event Rate was Reduced with Naproxen." The June 13, 2001 Press Release made, among others, the following materially false and misleading statements and/or omissions of material fact:

> The rates of cardiovascular events seen in patients taking VIOXX® were similar to those seen with both placebo and with the widely prescribed NSAIDs diclofenac, ibuprofen and nabumetone, while the event rate was lower for Naproxen compared to VIOXX®, said Alise Reicin, M.D., Senior Director, Merck Research Laboratories. The meta-analysis was strengthened by the fact that the majority of the data included in it was from studies six months or longer in duration.
>
> Aspirin blocks platelet aggregation by more than 90 percent by binding irreversibly to platelets. ***This property is believed to be responsible for its cardioprotective effect. It is reported in the scientific literature that Naproxen blocks platelet aggregation by about 90 percent if given every 12 hours at its recommended dose –as provided for in the studies with VIOXX®.*** This anti-platelet effect of Naproxen has not been observed among the other comparator NSAIDs; it has been reported that they do not block platelet aggregation in a sustained manner. (emphasis added)

44. The June 13, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the risk of cardiovascular events associated with VIOXX®. Among other things, the statements directly contradicted Defendant's e-mails and the results of internal studies like Study 090.

4. Merck Misrepresents Results of *Journal of American Medical Association* Study

45. On August 21, 2001, *Dow Jones Business News* published an article entitled "*JAMA* Article Suggests VIOXX® and Celebrex Raise Cardiovascular Risks" (the "First August 21, 2001 Article"). The First August 21, 2001 Article, which appears to have been based upon Dow Jones' receipt of an early copy of the article to be published in *JAMA*, discussed the Cleveland Clinic study and stated in pertinent part:

> An analysis of clinical trials suggests a potential increase in the rate of heart attack, stroke and other cardiovascular events among patients treated with VIOXX® from Merck & Co. Inc. (MRK) and Celebrex from Pharmacia Corp. (PHA) and Pfizer Inc. (PFE), according to an article in *The Journal of the American Medical Association*. Merck said in a prepared statement it stands behind the overall and cardiovascular safety profile and the favorable gastrointestinal profile of VIOXX®. The Company further contended, "***Extensive cardiovascular data already exist on VIOXX® and that these data, which weren't incorporated into the authors' analysis, suggest that there is no increase in the risk of cardiovascular events as a result of treatment with VIOXX®.***" (emphasis added)

46. The foregoing statement, failed to disclose material facts concerning the cardiovascular risks that VIOXX® presented and symbolized Defendant' efforts to suppress and distort the truth that VIOXX® was affirmatively dangerous.

47. Also on August 21, 2001, *Dow Jones Newswires* published an article entitled "VIOXX®, Celebrex Use Raises Cardiovascular Concerns-Study" (the "Second August 21, 2001 Article"). The Second August 21, 2001 Article further addressed the drug makers' responses to the findings of the Cleveland Clinic: "First, these drug makers do not believe their respective COX-2 inhibitors increases [sic] the risk of heart attack, stroke, unstable angina, and other cardiovascular events. The drug makers separately insist that their drugs are effective and safe, overall and with respect to the heart and cardiovascular system." The Second August 21, 2001

- Article described the comments of the senior director of cardiovascular clinical research at Merck:

> "We can't explain what is behind that observation and the authors point out the lower rate of cardiovascular events in those receiving Naproxen may be the result of the beneficial effects of Naproxen, which has aspirin-like profile in preventing platelet aggregation."
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> Understanding the relationship warrants further studies with placebo, said Demopoulos. ***But Merck has created an extensive body of cardiovascular data on VIOXX®, which was excluded from the author and analysis, which suggests VIOXX® doesn't increase the risk of cardiovascular events, she added.***

48. The Second August 21, 2001 Article failed to disclose material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX®. Instead, the Defendant's statement affirmatively misrepresented VIOXX®'s safety profile in a very direct contradiction of Defendant's internal e-mails and prior studies by Merck and others.

49. On August 23, 2001, the Company issued a press release (the "August 23, 2001 Press Release") entitled "Merck Stands Behind the Cardiovascular Safety Profile of VIOXX®," which stated in relevant part:

> Merck & Co., Inc. today, said the Company stands behind the overall and cardiovascular safety profile and the favorable gastrointestinal (GI) profile of VIOXX®. Merck believes VIOXX® is an appropriate and efficacious therapy for the relief of the signs and symptoms of osteoarthritis and the management of acute pain in adults.
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> The authors [of the *JAMA* article] say that more data are needed on the cardiovascular profile of COX-2 inhibitors. However, Merck believes that extensive cardiovascular data already exist on VIOXX® and that these data -- which were not incorporated into the author's analysis -- suggest that there is no increase in the risk of cardiovascular events as a result of treatment with VIOXX®.

50. The August 23, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the cardiovascular risks associated with VIOXX®, and misrepresented VIOXX®'s safety profile. The August 23, 2001 Press Release -- apparently

designed to falsely reassure both patients and prescribers that VIOXX® was safe -- directly contradicted Defendant's internal documents and other materials that demonstrated conclusively the statistically significant risks known to the Defendant even before VIOXX® was introduced.

5. Merck Refutes Statements in September 17, 2001 FDA Letter

51. On September 17, 2001, as described above, the FDA sent the Company a letter (the "September 17, 2001 FDA Letter") stating: "As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed your promotional activities and materials and has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations."

52. The September 17, 2001 FDA Letter went on to state:

> You have engaged in a promotional campaign for VIOXX® that minimizes the potentially serious cardiovascular findings that were observed in the VIOXX® Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for VIOXX®. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on VIOXX® were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (Naproxen).

53. The September 17, 2001 FDA Letter ordered the Defendant to stop using certain promotional materials and to send a letter to healthcare providers to correct any false impressions that came from Merck's marketing of VIOXX®.

54. The September 17, 2001 FDA Letter referenced the December 19, 1999 FDA Letter, adding that Merck's "misrepresentation of the safety profile for VIOXX® is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for VIOXX® that also misrepresented VIOXX®'s safety profile."

55. On September 24, 2001, Reuters published an article entitled "Merck VIOXX® Promotions Said Misleading on Safety," in which it described the September 17, 2004 FDA Letter. The September 24, 2001 article quoted a Merck spokeswoman, who stated that the Company was developing a response to the FDA that it planned to submit by October 1, 2001:

> **"We continue to stand behind the overall safety and cardiovascular safety of VIOXX®."**

56. Defendant's statements in this regard were false and misleading when made and contradicted Merck's internal documents and the results funded of Merck-funded studies like Study 090.

57. Each of the statements made from January 2001 through December 2001 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose material facts needed to make the statements made not misleading in light of the circumstances under which they were made. In fact, Defendant knew that VIOXX® was associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of VIOXX®" during 2001 were unfounded, because the Defendant knew that VIOXX® was associated with high cardiovascular risks;

- Merck's announcements refuting the Cleveland Clinic study results in *JAMA* and stating that the Company stood behind the safety profile of VIOXX® were unfounded, as the Defendant was aware that VIOXX® in fact caused an increase in adverse cardiovascular events;

- The Revised label for VIOXX® that Merck announced in April 2001 failed to disclose the severe cardiovascular risks that the Defendant had already observed in, among other things, Study 090 and VIGOR;

- The VIOXX® promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Defendant's deliberate efforts to conceal VIOXX®'s known risks;

• Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

• Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, the Defendant knew of the VIOXX®-related medical risks;

• Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs; and • On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• The Merck Defendant knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendant observed in Study 090; and

• VIOXX®'s safety profile was not "excellent" as the Merck Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

D. 2002 Events and False and Misleading Statements

58. In 2002, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Promotes New Changes to VIOXX®'s Label While Affirmatively Concealing the Significant Medical and Commercial Risks Associated with VIOXX®

59. On April 11, 2002, the Company issued a press release (the "April 11, 2002 Press Release") entitled "Merck Re-Issues New Release for VIOXX® -rofecoxib-With Prescribing Information Attached." The April 11, 2002 Press Release described a conference call held that day by Merck for pharmaceutical industry analysts, during which Merck re-released the announcement of FDA-approved changes to the label for VIOXX®. The April 11, 2002 Press Release stated in pertinent part:

> VIOXX® is now the first and only medicine that selectively inhibits the COX-2 enzyme that is proven to reduce the risk of developing clinically important

> gastrointestinal (GI) side effects in patients with or without risk factors for such GI side effects compared to the non-steroidal anti-inflammatory drug (NSAID) Naproxen. In VIGOR, VIOXX® 50 mg -- a dose two-times the highest recommended chronic dose -- significantly reduced serious GI side effects, including perforations, obstructions, ulcers and bleeds, by 54 percent compared to a commonly used dose of Naproxen (1,000 mg) in rheumatoid arthritis patients. The GI safety benefit compared to Naproxen, as shown in VIGOR, now appears as a modification to the GI Warning section of the prescribing information, a section included in the prescribing information for all NSAIDs, including those that selectively inhibit Cox-2.
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> "Merck is confident in the efficacy and safety profile of VIOXX®. VIGOR was a rigorous test of the GI safety of VIOXX® versus Naproxen and based on that study, the FDA has approved a modification to the standard GI warning section. Our label now reads: 'Although the risk of GI toxicity is not completely eliminated with VIOXX®, the results of the VIGOR study demonstrate that in patients treated with VIOXX®, the risk of GI toxicity with VIOXX® 50 mg once daily is significantly less than with Naproxen 500 mg twice daily,'" said Edward M. Scolnick, M.D., executive vice president, science and technology, and president, Merck Research Laboratories, Merck & Co., Inc.

60. The April 11, 2002 Press Release failed to disclose information known to the Defendant indicating that VIOXX® presented cardiovascular risks. The statements in the April 11, 2002 Press Release were precisely the type of statements condemned as false and misleading by the FDA in the letters it sent to Merck in December 1999 and September 2001.

61. On April 18, 2002, the *Associated Press Online* published an article (the "April 18, 2002 *AP Online* Article") entitled "Risks of Arthritis Drugs Studied," which stated in pertinent part:

> "There's growing suspicion that switching from aspirin to a more stomach-friendly arthritis drug could increase some people's risk of heart attacks -- and a study suggests the reason: a drug caused chemical imbalance that spurs blood clots. . . . VIOXX® maker Merck & Co. dismisses the study as irrelevant, because it is in mice and presumes an effect in the human body far larger than the drug actually causes." The April 18, 2002 *AP Online* Article further stated: "But the study looked at mice that had completely inhibited prostacyclin, while cox-2 drugs inhibit the chemical only half as much, said Merck scientist Dr. Alise Reicin. She said the study contributed no new information to the debate, but Merck plans further safety studies to deal with the issue, although she would not provide details."

• Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs; and

• On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• Merck knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendant observed in Study 090; and

• VIOXX®'s safety profile was not "excellent" as the Merck Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

E. 2003 Events and False and Misleading Statements

64. In 2003, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Continues to Tout Vioxx as Safe, Refuting the Results of a Study Linking Vioxx® to Cardiac Events

65. On October 30, 2003, *The Wall Street Journal* published an article (the "October 30, 2003 Article") entitled "Vioxx Study Sees Heart-Attack Risk--Merck Funded Research After Concerns Were Raised About Its Painkilling Drug." The article discussed a study conducted at Harvard University-affiliated Brigham & Women's Hospital in Boston, which found "an increased risk of heart attack, or acute myocardial infarction, compared with patients taking a competing painkiller, Celebrex, from Pfizer Inc. The researchers also found that VIOXX®, which has annual sales of $2.5 billion a year, was linked to an increased heart-attack risk compared with patients not taking any painkillers." The October 30, 2003 Article continued:

> The new study, Dr. Topol said, "greatly substantiates our concern about the cardiac side effects." He observed that the possible cardiac effects of Vioxx appear "worse with the higher doses." Merck discounted the

62. These statements were knowingly and demonstrably untrue when made. Defendant did not introduce new studies because it wanted to avoid the likelihood that additional adverse information would come to light.

63. Each of the statements made from January 2002 through December 2002 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose material facts needed to make the statements made not misleading in light of the circumstances under which they were made. In fact, Defendant knew that VIOXX® was associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

- At the time of the FDA's February 2001 Advisory Committee meeting, the Merck Defendant were aware of the cardiovascular risks associated with VIOXX®, and were aware that VIOXX® did not have an excellent safety profile;

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of VIOXX®" during 2002 were unfounded, because the Merck Defendant knew that VIOXX® was associated with high cardiovascular risks;

- Merck's announcements refuting the Cleveland Clinic study results in *JAMA* and stating that the Company stood behind the safety profile of VIOXX® were unfounded, as the Merck Defendant were aware that VIOXX® in fact caused an increase in adverse cardiovascular events;

- The Revised label for VIOXX® that Merck announced in April 2002 failed to disclose the severe cardiovascular risks that the Merck Defendant had already observed in, among other things, Study 090 and VIGOR;

- The VIOXX® promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Merck Defendant' deliberate efforts to conceal VIOXX®'s known risks, which continued in 2002;

- Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, Merck knew of the VIOXX®-related medical risks;

> findings. "Randomized clinical trials are the gold standard and this isn't such a trial," said Alise Reicin, Merck's executive director of clinical research. "In our placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo."

Defendant's comments were directly contradicted by Merck Internal documents, e-mails and materials, and Merck's own studies.

66. Continuing their aggressive campaign to suppress the truth about VIOXX®, Defendant acted quickly to assure it's consumers that VIOXX® was safe. On November 5, 2003, The Wall Street Journal published a Letter to the Editor by Defendant, (the "November 5, 2003 Wall Street Journal letter") entitled "Merck Stands Behind the Safety of Vioxx." In the November 5, 2003 Wall Street Journal letter, Defendant made, among others, the following materially false and misleading representations and/or omissions of material fact:

> Nothing is more important to Merck than the safety of its medicines. Your Oct. 30th story about an observational analysis of Vioxx was incomplete. The article discussed only the findings from this analysis where Vioxx appeared to have an unfavorable risk profile, but failed to report other findings from the same analysis that showed no statistically significant difference in the risk of heart attack for Vioxx compared with other commonly used anti-inflammatory drugs.
>
> The story also failed to report that another observational analysis presented at the same scientific meeting also showed no statistically significant difference in heart attacks between Vioxx and two widely used anti-inflammatory drugs, ibuprofen and diclofenac. *A complete reporting of the data presented might have remedied the mistaken impression left by the story.*
>
> Observational methods lack the rigor of randomized, controlled clinical trials, and have led the scientific community astray before. That is why observational studies must be interpreted with caution. *Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.*

The November 5, 2003 Wall Street Journal Letter failed to disclose what Defendants Kim and Merck knew: that VIOXX® was in fact associated with serious cardiovascular risks. More

specifically, Defendant had long before concluded that VIOXX® actually caused severely negative cardiovascular events -- a fact confirmed in internal Merck materials.

67. Each of the statements made from January 2003 through December 2003 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose the extent of the Defendant's knowledge that VIOXX® was in fact associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

- The Company was aware that Vioxx itself created an increased risk of heart attack, and that its explanation for the VIGOR study results--that the Vioxx patients suffered greater incidences of cardiovascular events because of cardioprotective qualities of Naproxen--was inaccurate;

- The Company's statements refuting the results of the Brigham & Women's Hospital Study finding an increased risk of heart attack in patients taking Vioxx were unfounded;

- The Company's announcements and press releases throughout 2003, stating that Merck 'stands behind the safety of Vioxx's were unfounded, because Merck knew that Vioxx, in fact, was associated with cardiovascular events and was therefore not safe;

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2003 were unfounded, because the Merck Defendants knew that Vioxx was associated with high cardiovascular risks;

- The Vioxx promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Merck Defendants' deliberate efforts to conceal Vioxx's known risks, which continued in 2003;

- Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the Vioxx-related medical risks;

- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs; and

• On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• Merck Defendants knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendants observed in Study 090; and

• Vioxx's safety profile was not "excellent" as the Merck Defendants claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

F. 2004 False and Misleading Statements

68. During 2004, prior to an after taking VIOXX® off the market, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts, some of which included the following,

69. On May 18, 2004, the American Health Line published an article (the "May 18, 2004 Article") entitled "Merck: Removes Author's Name from List in Vioxx Study." The May 18, 2004 Article described how when the Harvard-Brigham & Women's Study was originally presented, the list of authors included Merck epidemiologist Dr. Carolyn Cannuscio. However, when the study was published in the online edition of the American Heart Association's journal,

***

Worldwide sales of Vioxx, Merck's arthritis and pain medicine, were $653 million for the second quarter and $1.3 billion for the first six months. U.S. mail-order-adjusted prescription levels for Vioxx decreased by 5 percent during the quarter, as compared to the second quarter of 2003.

Following FDA approval for the acute treatment of migraine in late March, Vioxx is now approved for treating more types of painful conditions than any other coxib in the United States and remains the only coxib approved to relieve migraine pain and associated migraine symptoms. Merck continues to seek new uses for Vioxx to extend the clinical benefits of the product to new populations. A supplemental NDA for Vioxx is under review by the FDA for the treatment of juvenile rheumatoid arthritis. Outside of the United States, Vioxx continues to be

> the best-selling arthritis and pain medicine. Indications for Vioxx for migraine and juvenile rheumatoid arthritis also are being sought outside of the United States.

The July 21, 2004 Press Release failed to disclose information known by Merck concerning the cardiovascular risks associated with VIOXX® and the impact of those risks and related liabilities on the medical and commercial viability of VIOXX®.

70. The May 18, 2004 Article quoted Merck spokesperson May Elizabeth Black as stating:

> Merck disagreed with the conclusions and didn't think it was appropriate to have a Merck author. Nancy Santanello, Merck executive director of epidemiology and Cannuscio's manager, said that the study had 'serious limitations' because it was 'not able to control completely for the differences between the groups.' Santanello added that Merck is currently conducting research on Vioxx and heart attacks.

The Defendant's statements were false and misleading because, among other things, it misrepresented the true facts of the Vioxx-related risks and falsely stated that Merck was conducting research on Vioxx and heart attacks.

1. Merck Publicly Discredits Results of Kaiser Permanente Study

71. On August 26, 2004, *Bloomberg News* published an article (the "August 26, 2004 Bloomberg Article") entitled "Vioxx Raises Heart Risk, Study Says; Merck disputes Tests that Favor Pfizer's Celebrex." The article stated in pertinent part:

> Merck & Co.'s Vioxx painkiller increases the chance of heart attack and death from cardiac arrest more than Pfizer Inc.'s Celebrex, according to a study by a U.S. Food and Drug Administration investigator.
>
> The difference in heart risk was statistically significant between a recommended dose of Vioxx, 25 mg a day or less, and Celebrex, according to results the FDA's David Graham presented at a meeting of the International Society for Pharmacoepidemiology in France.
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> ***

> We found that Celebrex appears to be safer from a cardiac perspective at the lower dose, Graham said in a telephone interview from France. If there's a difference in risk between Celebrex and Vioxx, that's an important public health question, because you have two drugs being used for the same gastrointestinal effect.
>
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> Merck disagrees with the results from Graham and his colleagues, spokeswoman Mary Elizabeth Blake said. Conclusions from that type of examination don't carry as much weight as results from a study comparing two groups of patients taking the medicines for a set period of time, she said.
>
> ***
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> Merck researchers and officials have said the difference between Vioxx and other painkillers occurs because a comparison drug, an anti-inflammatory called Naproxen, protects the heart. The FDA funded study found the contrary--that Naproxen raises heart risk by 18 percent.

The Defendant's statements attributed were false when made in that the Defendant knew before the drug was introduced that VIOXX® caused serious cardiovascular events.

72. An article dated August 26, 2004 published by the *Associated Press* (the "First August 26, 2004 AP Article") entitled "Merck Disagrees with Vioxx Analysis," stated that [p]harmaceutical company Merck & Co. "strongly" disagreed Thursday with the conclusions of a Food and Drug Administration-funded study that said use of the company's arthritis pain reliever Vioxx increased the risk of heart attacks. At the same time, and unbeknownst to the public, Merck used all of its influence with the FDA to attempt to delay and/or thwart publication by Graham of the results of this study.

73. An article dated August 26, 2004 published by the Associated Press (the "Second August 26, 2004 AP Article") entitled "Merck Defends Arthritis Drug's Safety After Critical FDA Study," announced that "Merck shares fell 97 cents, or two percent, to $45.05 Thursday"

following the release of the FDA study results showing Vioxx's association with a high risk of cardiovascular events.

74. The Second August 26, 2004 AP Article discussed the Company's reaction to the release of the above-described FDA study:

> Pharmaceutical giant Merck & Co. insisted Thursday its blockbuster arthritis drug Vioxx is safe despite new evidence the popular pain pill increases risk of serious heart problems, even death, particularly at high doses.
>
> ***
>
> Alise Reicin, vice president of clinical research at Whitehouse Station-based Merck, said Vioxx is safe and effective, and numerous earlier studies comparing it to a dummy pill found 'no difference in the risk of having a serious cardiovascular events.' The drug was tested on about 10,000 patients before it went on sale. Reicin said the new study was not as rigorous because it was observational, rather than a controlled experiment in which randomly chosen patients get different treatments and are followed over time.
>
> ***
>
> Reicin, the Merck research executive, said half of the six observational studies on Vioxx to date found it did not increase heart complications.

Significantly, the statements attributed to Defendant all fail to disclose the significant cardiovascular risks caused by VIOXX® -- risks that Defendant was especially familiar with.

75. An article dated August 26, 2004 published by the *Associated Press* (the "Third August 26, 2004 AP Article") entitled "FDA Voices Concerns Over Arthritis Drug" quoted Defendant's analysis of the above-described study results: "Observational analyses do not have the rigor of randomized, controlled clinical trials. . . . Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of Vioxx." Criticism of methodology notwithstanding, Defendant's efforts to refute Graham's study were wholly unavailing because the findings were completely consistent with all of the information in Merck's files, including the results of the 1998 Study 090, the 2000 VIGOR

study, the 2001 JAMA study, the Vanderbilt UnitedHealth Care and Kemper studies and the APPROVE study which was to be terminated less than one month later.

76. On September 8, 2004, the *Dow Jones News Service* (the "September 8, 2004 article") published an article entitled: "Merck: FDA OKs Vioxx for Once-Daily Treatment of Juvenile Rheumatoid Arthritis; First and Only COX-2 Specific Inhibitor Approved for Use in Children As Young as Two." The article announced the FDA's approval of Vioxx for the treatment of juvenile rheumatoid arthritis. Merck continued to press for the FDA's approval to prescribe Vioxx for "children as young as two" despite the fact that Merck knew that Vioxx caused serious cardiovascular damage and despite the fact Merck would later withdraw Vioxx from the market during the very month which it received approval to use this deadly drug on children.

2. The Withdrawal of Vioxx and Merck's Continued Campaign of Concealment

77. On September 30, 2004, Defendant announced that it was withdrawing VIOXX® worldwide, citing as its reason the results of the APPROVe trial. However, the results of the APPROVe study were nothing new to Merck. These results were wholly consistent with studies dating back to the 1998 Study 090 and confirmatory VIGOR study in early 2000.

78. Following the announcement, Defendant continued to conceal its prior knowledge of the extent of the cardiovascular risks associated with Vioxx. For example, that same day, Defendant held a press conference to explain its decision to withdraw Vioxx. Its CEO gave the following statements:

> I'll just give you a quick summary here. The reason that we're here today is because this morning, Merck is announcing a voluntary worldwide withdrawal of Vioxx, our Cox-2 inhibitor for arthritis and pain. This decision is the result of new data from a three-year placebo controlled study which was designed to evaluate the possible use of Vioxx in